

I. Status of the Claims

Claims 39 and 41-55 are pending in the application. New claims 56-60 have been added in the amendments above. Support for new claim 56 may be found, for example, at claim 39 and throughout the specification, figures and abstract as originally filed. Support for new claims 57-58 may be found, for example, at page 38, line 13 to page 39, line 14, at FIG. 23 and throughout the specification, figures and abstract as originally filed. Support for new claims 59-60 may be found, for example, at page 11, lines 7-22, at page 15, lines 19-22, at page 32, lines 16-20, and throughout the specification, figures and abstract as originally filed.

II. Enclosed CD-ROM with MPEG files

A CD-ROM that included two MPEG files was submitted on December 9, 2004. During a telephonic interview on March 23, 2005, Examiner Ragonese indicated that the CD-ROM submitted on December 9, 2004 was never forwarded to her for review.

To further facilitate the Examiner's understanding of the differences between the pending claims and the documents cited by the Examiner, an additional copy of the CD-ROM that was submitted on December 9, 2004 is enclosed herewith. The CD-ROM includes the following MPEG files:

- (a) Paravaginal Defect Demo 1; and
- (b) Laparoscopic Paravaginal Repair.

These files may be viewed with any media player such as Windows Media Player 10. Should the Examiner wish to discuss the contents of the CD-ROM, the Examiner is invited to call the undersigned at the phone number listed below.

III. Interview Summary

In a telephonic interview on March 23, 2005, Applicant, Dr. Peter Rosenblatt, along with the undersigned and Examiner Ragonese discussed the differences between the pending claims and the citations relied on by the Examiner in the Office Action mailed on January 26, 2005. In particular, Applicant pointed out that none of the citations were directed to paravaginal or vaginal repair using the particular anatomical structures recited in the claims. Applicant also pointed out that none of the citations were directed to paravaginal repair or vaginal repair of a cystocele (fallen bladder). Applicant further pointed out that while incisions could be made in

the method of claim 39, the lateral pelvic sidewall is not exposed through a surgical incision in a vaginal wall using the method defined by claim 39. Applicant also pointed out that no incision would be made using the methods defined by each of claims 53-55. Thus, the claims as presented are patentable over the citations of record.

Applicant also pointed out that the citations were neither directed to paravaginal repair nor were they directed to the use of a soft tissue fixation device that did not exit the lateral pelvic sidewall. Accordingly, a claim reciting either one of these elements is allowable. Claims 59 and 60 are presented above, and recite "penetrating the lateral pelvic sidewall with the soft tissue fixation device without exiting the lateral pelvic sidewall." In view of the above, each of claims 59 and 60 is allowable.

The Examiner indicated that a claim similar to claim 39 that included the terms "repair" or "paravaginal repair" in the body of the claim appeared to be allowable over the citations of record. In view of the above and because the claims as presented are patentable over the citations of record, Applicant has presented new claims 56-58 in the amendments above. Claim 56 is similar to claim 39 and also recites the element "performing a paravaginal repair by approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall, without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall." Claim 56 is allowable, as is claim 57 which depends from claim 56 and recites that "a cystocele is repaired paravaginally." Claim 58 depends from claim 39 and recites that a "cystocele is repaired paravaginally." Claim 58 is allowable.

Also during the telephonic interview, the Examiner agreed that the rejection of claims 44-45 in paragraph 15 of the Office Action was improper. As acknowledged by the Examiner, the particular steps recited in claims 44 and 45 cannot be properly considered a species.

Applicant respectfully requests reconsideration of the claims.

IV. Claims 41, 47-48 and 54 meet the Written Description Requirement of 35 U.S.C.

Applicant traverses the rejection of claims 41, 47-48 and 54 under § 112, first paragraph. No additional reasoning or argument was presented in response to Applicant's remarks in the amendment filed on December 3, 2004. That is, the § 112, first paragraph rejection presented in the office action mailed on January 26, 2005 is exactly the same as the § 112, first paragraph

rejection presented in the office action mailed on October 3, 2004. Applicant's remarks should be substantively addressed and properly considered.

Notwithstanding the above, it is well established that the subject matter of a claim need not be described literally in order for the disclosure to satisfy the written description requirement. Instead, the test is does the disclosure of the application relied upon "reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). The claims may be supported by words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

When this test is properly applied to claims 41, 47, 48 and 54, each of claims 41, 47, 48 and 54 is fully supported by the specification, figures, abstract and claims as originally filed (hereafter collectively referred to as "the disclosure"). Support for claim 41 may be found, for example, at page 26, line 16 to page 27, lines 8-9, page 27, lines 8-9 (stating "a surgical incision is not created to expose the anchoring tissues"), page 27, line 23, FIGS. 12-14 and throughout the disclosure. Support for claim 47 may be found, for example, at page 27, lines 16-23, page 39, lines 16-23, at original claim 33 and throughout the disclosure. Support for claim 48 may be found, for example, page 39, lines 4-5, page 39, line 22 and throughout the disclosure. Support for claim 54 may be found, for example, at FIGS. 12-14, 23 and at page 11, lines 16-19, page 27, lines 8-9 and throughout the disclosure.

With particular reference to claim 54, claim 54 has been rejected under 35 U.S.C. § 112, first paragraph, but no objective evidence that challenges the validity of claim 54 has been provided in any of the office actions. The Examiner bears the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in Applicant's disclosure a description of the invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). No such evidence has been provided regarding claim 54, and, until such evidence is provided, claim 54 presumptively meets the requirements of 35 U.S.C. § 112, first paragraph.

In view of the above, each of claims 41, 47, 48 and 54 meets the written description requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully requests withdrawal of the rejection.

V. Claims 39, 41, 46-49 and 52-55 are Patentable over Kovac

Applicant traverses the rejection of claims 39, 41, 46-49 and 52-55 under § 102(e), or § 103(a), over Kovac (US 6,039,686). The disclosure of Kovac does not anticipate, or render obvious, any of claims 39, 41, 46-49 and 52-55.

Kovac is directed to suspension of the urethra using a sling anchored to the pubic bone (hard tissue). See Abstract; Col. 3, lines 11-13 and lines 53-56; Col. 5, lines 52-56; and claim 1 of Kovac. Kovac is not repairing the underlying cause of the urinary incontinence. Instead, Kovac is suspending the urethra in an attempt to relieve the symptoms of urinary female incontinence. See, for example, the Abstract of Kovac. Also, Kovac is neither approximating existing anatomical structures to accomplish a repair, nor is Kovac approximating soft tissues. In fact, Kovac even teaches away from using existing anatomical structures. See Col. 8, lines 2-10 of Kovac. In addition, Kovac makes a pair of divergent incisions in the anterior vaginal wall to access the urethra and pubic bones. See Col. 3, lines 32-34 and Col. 6, lines 10-18 of Kovac.

Such disclosure differs markedly from claim 39, which is directed to a paravaginal repair method performed “without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall.” In particular, Kovac is not directed to paravaginal repair, and Kovac does not approximate the particular anatomical structures recited in claim 39. Thus, Kovac does not anticipate, or render obvious, a method of surgical paravaginal repair comprising placing a soft tissue fixation device vaginally through an insertion device adapted for inserting the soft tissue fixation device, and approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall (as the term “surgical incision” is understood by the person of ordinary skill in the art (see, e.g., page 27, lines 9-14 of the specification)).

With particular reference to the phrase “placing a soft tissue fixation device vaginally through an insertion device,” as recited in claim 39, the burden of establishing inherency, or obviousness, lies with the Examiner. Inherency requires a demonstration that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would

be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). No proper objective evidence has been presented demonstrating that Kovac necessarily discloses an insertion device, as that term is used in the present claims, or that it would be obvious to use an insertion device in view of Kovac. Therefore, claim 39 is patentable over Kovac.

Regarding claim 41, Kovac does not anticipate, or render obvious, a method of surgical repair using a soft tissue fixation device and an insertion device, wherein the surgical repair is one of a paravaginal repair and a vaginal repair, the method comprising placing the soft tissue fixation device vaginally through the insertion device, and approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. Kovac is not directed to paravaginal repair or vaginal repair, and Kovac does not approximate the particular anatomical structures recited in claim 41.

With particular reference to the phrase “placing a soft tissue fixation device vaginally through an insertion device,” as recited in claim 41, the burden of establishing inherency, or obviousness, lies with the Examiner. Inherency requires a demonstration that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). No proper objective evidence has been presented demonstrating that Kovac necessarily discloses an insertion device, as that term is used in the present claims, or that it would be obvious to use an insertion device in view of Kovac. Therefore, claim 41 is patentable over Kovac.

Regarding claim 52, the disclosure of Kovac does not anticipate, or render obvious, a method of soft tissue repair, wherein the repair is at least one of a paravaginal repair and a vaginal repair, the method comprising penetrating an intact outer wall of a first soft tissue, penetrating a second soft tissue, and affixing said first soft tissue to said second soft tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue. Kovac does not affix a first soft tissue to a second soft tissue. Instead, Kovac suspends the urethra using a sling anchored to pubic bone (hard tissue). Therefore, claim 52 is patentable over Kovac.

Claim 53 depends from claim 39, each of claims 46-49 and 54 depends directly or indirectly from claim 41, and claim 55 depends directly from claim 52. The dependent claims are patentable over Kovac for at least the same reasons provided herein in reference to claims 39, 41 and 52.

In addition, claims 53-55 have been misinterpreted. On page 5 of the Office Action, the Examiner asserts that "Regarding claims 53-55, Kovac discloses that as applied to claim 41, as well as it is obvious, if not inherent, to do so without making an incision in the pelvic sidewall." This assertion is inapposite when claims 53-55 are properly read.

First, claim 53 depends from claim 39 and not claim 41, and claim 55 depends from claim 52 and not claim 41. Second, each of claims 53-55 recites that no incision is made. That is, claim 53 recites that no incision is made in performing the paravaginal repair method of claim 39, claim 54 recites that no incision is made in performing the repair method of claim 41, and claim 55 recites that no incision is made in performing the repair method of claim 52. Claims 53-55 are different than the methods of Kovac, which use a pair of divergent incisions made in the anterior vaginal wall to access the urethra and pubic bones. See Col. 3, lines 32-34 and Col. 6, lines 10-18 of Kovac. Accordingly, the rejection of claims 53-55 is improper.

In view of the above, the rejection of claims 39, 41, 46-49 and 52-55 over Kovac should be withdrawn.

VI. Claims 39, 41, 46-49 and 52-55 are Patentable over Benderev

Applicant traverses the rejection of claims 39, 41, 46-49 and 52-55 under § 102(e), or § 103(a), over Benderev (US 6,500,194). The disclosure of Benderev does not anticipate, or render obvious, any of claims 39, 41, 46-49 and 52-55.

Benderev discloses a method similar to the method of Kovac. Benderev is directed to suspension of the bladder neck using a staple or sutures attached to a suture support. A bone anchor is used to fix the suture to bone (hard tissue). See Example III in Col. 38 and 39. Thus, Benderev's methods are designed to suspend the bladder neck, and such disclosure does not anticipate, or render obvious, the paravaginal repair and vaginal repair methods defined by each of claims 39, 41, 46-49 and 52-55. Moreover, Benderev fails to disclose, approximation of the particular anatomical structures recited in claims 39 and 41 in order to perform a paravaginal

repair or a vaginal repair, and does not disclose affixing a first soft tissue to a second soft tissue, using the method defined by claim 52.

Regarding claim 39, Benderev does not anticipate, or render obvious, a method of surgical paravaginal repair comprising placing a soft tissue fixation device vaginally through an insertion device adapted for inserting the soft tissue fixation device, and approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall. As discussed above, Benderev suspends the bladder neck and does not disclose approximation of the particular anatomical structures recited in claim 39. Therefore, claim 39 is patentable over Benderev.

Regarding claim 41, Benderev is insufficient to anticipate, or render obvious, a method of surgical repair using a soft tissue fixation device and an insertion device, wherein the surgical repair is one of a paravaginal repair and a vaginal repair, the method comprising placing the soft tissue fixation device vaginally through the insertion device, and approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium. As discussed above, Benderev suspends the bladder neck and does not disclose approximation of the particular anatomical structures recited in claim 41. Therefore, claim 41 is patentable over Benderev.

Regarding claims 47-48, it is improper to assert obviousness or inherency without providing some objective evidence. Claims 47 and 48 recite specific anatomical structures. An electronic word search of the specification of Benderev reveals that the terms “arcus tendineus fascia” and “levator ani” are not disclosed. It is improper to assert obviousness, or inherency, without providing some objective evidence or reasoning. No such objective evidence or reasoning has been provided regarding claims 47-48. Thus, no case of obviousness or inherency has been properly established.

Regarding claim 49, as discussed above, it is improper to assert obviousness or inherency without providing some objective evidence. Claim 49 recites several medical conditions which are simply not disclosed in Benderev. An electronic word search of the specification of Benderev reveals that the terms “prolapse,” and “urethrocele” are not found in Benderev. Because it is improper to assert obviousness, or inherency, without providing some objective evidence or reasoning, and because no such objective evidence or reasoning has been provided

regarding the terms “prolapse,” and “urethrocele” in claim 49, no case of obviousness or inherency has been properly established.

Regarding the terms “rectocele” and “cystocele,” which are also recited in claim 49, these terms are disclosed once at Col. 35, lines 9-11 of Benderev. See text stating “two patients had modified endoscopic bladder neck suspensions with concomitant vaginal procedures such as rectocele and/or cystocele repairs.” This text, however, implies that a bladder neck suspension procedure, such as the one disclosed in Benderev, is not used to accomplish a rectocele repair or a cystocele repair. Thus, Benderev does not anticipate claim 49 or render claim 49 obvious.

Regarding claim 52, the disclosure of Benderev does not anticipate, or render obvious, a method of soft tissue repair, wherein the repair is at least one of a paravaginal repair and a vaginal repair, the method comprising penetrating an intact outer wall of a first soft tissue, penetrating a second soft tissue, and affixing said first soft tissue to said second soft tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue. As discussed above, Benderev is directed to suspension of the bladder neck using a staple or sutures attached to a suture support. A bone anchor is used to fix the suture to bone (hard tissue). Therefore, claim 52 is patentable over Benderev.

Claim 53 depends from claim 39, each of claims 46-49 and 54 depends directly or indirectly from claim 41 and claim 55 depends directly from claim 52. The dependent claims are patentable over Benderev for at least the same reasons provided herein in reference to claims 39, 41 and 52.

In addition, claims 53-55 have been misinterpreted. On page 6 of the Office Action, the Examiner asserts that “Regarding claims 53-55, Benderev et al. discloses that as applied to claim 41, as well as it is obvious, if not inherent, to do so without making an incision in the pelvic sidewall.” This assertion is inapposite when claims 53-55 are properly read.

First, claim 53 depends from claim 39 and not claim 41, and claim 55 depends from claim 52 and not claim 41. Second, each of claims 53-55 recites that no incision is made. That is, claim 53 recites that no incision is made in performing the paravaginal repair method of claim 39, claim 54 recites that no incision is made in performing the repair method of claim 41, and claim 55 recites that no incision is made in performing the repair method of claim 55. In view of the above, the rejection of claims 53-55 is improper.

In view of the above, the rejection of claims 39, 41, 46-49 and 52-55 over Benderev should be withdrawn.

VII. Claims 42-43 are Patentable over Kovac or Benderev in view of Thompson

Applicant traverses the rejection of claims 42-43 under § 103(a) over Kovac or Benderev in view of Thompson (US 5,591,163).

As discussed above in Sections V. and VI., Kovac and Benderev do not anticipate, or render obvious, any of claims 39, 41, 46-49 and 52-55. Each of claims 42 and 43 depends from claim 41. Thus, the combination of Kovac with Thompson, or Benderev with Thompson, likewise is insufficient to render either of claim 42 or 43 obvious. Even if this were not the case, the combination of Kovac and Thompson, or Benderev and Thompson, is still insufficient to render either of claims 42 or 43 obvious.

Thompson is designed to treat stress incontinence by suspending the urethra from an anchor attached above the urethra. See Abstract; Col. 3, lines 62-64; Col. 4, lines 48-49 of Thompson. Thompson uses an anchor secured in the pubic bone (hard tissue) to suspend the urethra. See Col. 6, lines 1-8. The tails of sutures are tied together to form a sling to suspend the urethra. See Col. 6, lines 8-19. Accordingly, the methods of Thompson, which use a bone anchored sling, are similar to the methods of Kovac and Benderev, and Thompson cannot be properly applied to either of claims 42 or 43.

In view of the above, the rejection of claims 42 and 43 over the combination of Kovac and Thompson, or Benderev and Thompson, should be withdrawn.

VIII. Claims 44-45 and 50-51 are Patentable over Kovac or Benderev

Applicant traverses the rejection of claim 44-45 and 50-51 under § 103(a) over Kovac or Benderev.

Regarding claims 44 and 45, the Examiner indicated during the telephonic interview on March 23, 2005 that the rejection was improper and acknowledged that claims 44-45 were not directed to a “particular species.” Accordingly, claims 44 and 45 have not been properly rejected over any citations, and claims 44-45 are allowable. A Notice to this effect is respectfully requested.

Regarding claims 50 and 51, the Examiner has made the unsupported assertion that because MRI, CT scans, etc. are well known, the subject matter of each of claims 50 and 51 is somehow obvious. Such an unsupported assertion does not establish obviousness.

Instead, it is well established that the test for obviousness includes three parts. First, the citation(s) must teach or suggest all of the claimed features. Second, there must be some specific suggestion or motivation, either in the cited citation(s) or in the knowledge generally available to one of ordinary skill in the art, to modify the citation(s). Third, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applying the obviousness test to claims 50 and 51, first and as discussed above, neither Kovac nor Benderev teach or suggest all the features of claim 41. Because each of claims 50 and 51 depends directly from claim 41, Kovac and Benderev necessarily cannot teach or suggest all the features of claim 50 or claim 51. Second, no objective evidence has been identified that Kovac or Benderev teaches or suggests use of the modalities listed in each of claims 50 and 51. When no such teaching or suggestion exists, obviousness is not established. Third, no reasonable expectation of success has been identified. Accordingly, none of the three criteria for establishing obviousness has been met in the present case.

In view of the above, the rejection of claims 44-45 and 50-51 over Kovac or Benderev is improper and should be withdrawn.

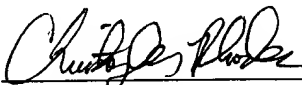
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IX. Conclusion

For the reasons provided above, the rejections of claims 39 and 41-57 are improper and should be withdrawn.

Applicant respectfully requests withdrawal of all rejections and issuance of a Notice of Allowance.

Respectfully submitted,
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